

SEP 19 2000

## 510(k) Summary

K001093

### General Information:

This 510(k) is to provide notification of substantial equivalence for the Candela SPTL-1b Pulsed Dye Laser System, which is substantially equivalent to previously marketed devices intended for the treatment of benign cutaneous vascular lesions (K861179 and K882243), the treatment of benign vascular lesions in gynecology (K900858) and the treatment of benign cutaneous lesions (verrucae, scars) (K931762).

Classification:	Class II (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)
Trade Name:	Candela SPTL-1b Pulsed Dye Laser
Common Name:	Dermatology Laser
Predicate Devices:	Candela GentleLase SPTL laser cleared under 510(k)s K861179, K882243, K900858, K931762 and the Laser cleared under 510(k) notification numbers

### Description:

The Candela SPTL-1b Pulsed Dye Laser utilizes a flash lamp excited pulsed dye laser optimized for the treatment of benign vasculature lesions. The SPTL laser system delivers pulses of laser energy through an optical fiber and hand piece at a wavelength that passes through the dermis and epidermis and is absorbed by the hemoglobin in the abnormal vessels of the lesion, rather than the surrounding tissue. The absorbed laser energy is converted to heat, causing coagulation of the target vessels, which are not subsequently regenerated. The pulse width used is long enough to produce controlled coagulation, but short enough to avoid thermal damage to the surrounding tissue. To date, successful treatment has been accomplished in many thousand of patients with disfigurements such as port wine stain, facial telangiectasia, and other similar vascular skin lesions, as well as abnormal vascular lesions in gynecology. The Candela SPTL Pulsed Dye Laser is designed with five major components:

1. High voltage power supply and modulator system
2. Optical laser head
3. Circulator system
4. Optical delivery system
5. Software control system

The Candela SPTL Pulsed Dye Laser is equipped with safety interlock systems to protect patients and operators. Users of the device make selections from an onboard control panel to regulate operation during treatment.

The intended use of the laser system is the photocoagulation of benign cutaneous vascular lesions, benign cutaneous vascular lesions in gynecology and benign cutaneous lesions, such as warts, scars and psoriasis.

### Testing:

Pulsed Dye Lasers have been tested in five clinical studies at five sites for the treatment of psoriatic plaque and the results of those studies have been published. A total of 85 patients were involved with these studies. Results show that treatment with the pulsed dye laser can clear the psoriatic plaque with multiple treatments. All sites report that the majority of laser treated patients demonstrated improvement. One site reported a

statistically significant reduction in erythema, scale and induration with patients remaining in remission during a 13 month follow up period.

One study reported no adverse effects, another study reported black scabs and one case of atrophic scarring with healing. A third study reported haemorrhagic scabs in two patients, which resolved within 16 weeks and one incidence of a hyperpigmented macule. An additional study reported mild scarring, textural changes, and mild hypo and hyperpigmentation. This investigator reported significant improvement of erythema, scale, and induration of plaques. The last study reported two cases of superficial haemorrhagic ulcerations with other patients showing slight redness followed by a slight to moderate post-inflammatory hyper and hypo-pigmentation.

Summary of Substantial Equivalence:

The Candela SPTL Pulsed Dye Lasers have an equivalent intended use, utilize the same operating principles and match key design aspects, including similar spot size, the same wavelength and the same maximum delivered power as the predicate device.

On the basis of similarities in methods of assembly, method of operation, intended uses, and clinical data Candela believes that its Candela SPTL Pulsed Dye Laser System is substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 19 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Joan Clifford  
Clinical Research Manager  
Candela Corporation  
530 Boston Post Road  
Wayland, Massachusetts 01778

Re: K001093  
Trade Name: Candela SPTL-1b Pulsed Dye Laser  
Regulatory Class: II  
Product Code: GEX  
Dated: July 10, 2000  
Received: July 11, 2000

Dear Ms. Clifford:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K001093

Device Name: Candela SPTL-1b Pulsed Dye Laser

Indications For Use:

The Candela SPTL-1b Pulsed Dye Laser is indicated for the following uses:  
the photocoagulation of benign cutaneous vascular lesions, benign cutaneous  
vascular lesions in gynecology and benign cutaneous lesions, such as warts,  
scars and psoriasis.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Lochner.  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K001093

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional format 1-2-96)